

Mr. Ronald A. Milner, Chief Operating Officer
Office of Civilian Radioactive Waste Management
U. S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION'S OBSERVATION AUDIT
REPORT NO. OAR-02-03, "OBSERVATION AUDIT OF THE OFFICE OF
CIVILIAN RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY
ASSURANCE, AUDIT NO. EM-ARC-02-01"

Dear Mr. Milner:

I am transmitting the U.S. Nuclear Regulatory Commission's (NRC's) Observation Audit Report (No. OAR-02-03) of the U.S. Department of Energy's (DOE's) Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance's (OQA's), audit of DOE's Office of Environmental Management (EM), Office of Safety, Health and Security (EM-5). This audit was conducted on December 11 through 14, 2001, at the EM offices in Germantown, Maryland.

The purpose of this audit was to evaluate the effectiveness of EM-5's implementation of the High-Level Waste (HLW) Quality Assurance (QA) Program and to determine if applicable requirements of the OCRWM Quality Assurance Requirements and Description (QARD) were being met. The scope of the audit included evaluating the implementation of the QARD for EM-5 activities controlling the processing of HLW at various sites such as the Savannah River Operations Office Defense Waste Processing Facility and the Hanford Office of River Protection. Also, the audit evaluated action taken as a result of the findings and recommendations identified during a previous OQA audit conducted in June 2001.

The NRC observers (observers) determined that this audit was effective in identifying potential deficiencies and recommending improvements for the EM-5 activities reviewed. During the conduct of the audit, both the OQA audit team (audit team) and the observers independently reviewed applicable documents, procedures, and activities within the audit's scope.

During the audit, the audit team identified two potential deficiencies. One potential deficiency identified that the files for certain memoranda of agreements, between affected organizations, did not contain the revision history required by applicable EM-5 procedures. The second potential deficiency identified the following three problems within the area of training: 1) Certain training files were missing experience and education documentation; 2) QARD requirements for position descriptions were not met; and 3) Training matrixes do not address job responsibilities and functions.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. However, during the conduct of the audit, the observers initiated an audit observer inquiry (AOI) identifying concerns about the current practice used by OQA and EM-5 for reviewing and approving exceptions to the QARD.

Additionally, the observers discussed OQA's and EM-5's roles in overseeing contractor activities at the various EM field offices. The EM-5 QA Director explained that EM-5 may no longer participate in audits of site contractors and that the field offices may have the responsibility to perform these audits. The observers recommended that, should EM-5 decide not to participate in audits of site contractors, either OQA or the EM-5 QA organization evaluate the need to oversee the initial field office audits and to determine the effectiveness of these audits.

Although the audit team identified two potential deficiencies, the observers believe that the audits performed by EM-5 were well-planned and adequately evaluated the implementation of the QARD at the various HLW processing sites. NRC will continue to interface with OCRWM and follow the progress that EM-5 is making to address the issues identified during this audit.

A written response to this letter and the enclosed report is not required; however, we do request that you respond to AOI No. EM-ARC-02-01, Sequence No. 1, provided to the audit team during audit and discussed in the attached report. If you have any questions, please contact Larry L. Campbell, of my staff at (301) 415-5000.

Sincerely,

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-02-03, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Office of Quality Assurance,
Audit No. EM-ARC-02-01"

cc: See attached list

Letter to R. Milner from C.W. Reamer dated _____

cc:

R. Loux, State of Nevada	R. Massey, Lander County, NV
S. Frishman, State of Nevada	J. Pitts, Lincoln County, NV
L. Barrett, DOE/Washington, DC	M. Baughman, Lincoln County, NV
A. Brownstein, DOE/Washington, DC	A. Funk, Mineral County, NV
S. Hanauer, DOE/Washington, DC	J. Shankle, Mineral County, NV
C. Einberg, DOE/Washington, DC	L. Bradshaw, Nye County, NV
J. Carlson, DOE/Washington, DC	M. Murphy, Nye County, NV
N. Slater, DOE/Washington, DC	J. McKnight, Nye County, NV
A. Gil, YMPO	D. Weigel, GAO
R. Dyer, YMPO	W. Barnard, NWTRB
S. Brocoum, YMPO	R. Holden, NCAI
R. Davis, YMPO	A. Collins, NIEC
S. Mellington, YMPO	R. Arnold, Pahrump Paiute Tribe
C. Hanlon, YMPO	J. Larson, White Pine County
T. Gunter, YMPO	R. Clark, EPA
K. Hess, BSC	F. Marcinowski, EPA
D. Krisha, BSC	R. Anderson, NEI
S. Cereghina, BSC	R. McCullum, NEI
N. Williams, BSC	S. Kraft, NEI
M. Voegele, BSC/SAIC	J. Kessler, EPRI
R. Henning, BSC	D. Duncan, USGS
B. Price, Nevada Legislative Committee	R. Craig, USGS
J. Meder, Nevada Legislative Counsel Bureau	W. Booth, Engineering Svcs, LTD
I. Navis, Clark County, NV	L. Lehman, T-REG, Inc
E. von Tiesenhausen, Clark County, NV	S. Echols
A. Kalt, Churchill County, NV	N. Rice, NV Congressional Delegation
G. McCorkell, Esmeralda County, NV	T. Story, NV Congressional Delegation
L. Fiorenzi, Eureka County, NV	J. Reynoldson, NV Congressional Delegation
A. Johnson, Eureka County, NV	S. Joya, NV Congressional Delegation
A. Remus, Inyo County, CA	J. Pegues, City of Las Vegas, NV
M. Yarbrow, Lander County, NV	R. Bahe, Benton Paiute Indian Tribe
I. Zabarte, W.S.N.C.	C. Bradley, Kaibab Band of Southern Paiutes
C. Anderson, Las Vegas Paiute Tribe	R. Joseph, Lone Pine Paiute-Shoshone Tribe

J. Birchim, Yomba Shoshone Tribe
L. Jackson, Timbisha Shoshone Tribe
C. Meyers, Moapa Paiute Indian Tribe
V. Miller, Fort Independence Indian Tribe
A. Bacock, Big Pine Paiute Tribe of
the Owens Valley
R. Quintero, Inter-Tribal Council of Nevada
(Chairman, Walker River Paiute Tribe)
M. Bengochia, Bishop Paiute Indian Tribe
J. Egan, Egan & Associates, PLLC

L. Tom, Paiute Indian Tribes of Utah
E. Smith, Chemehuevi Indian Tribe
J. Charles, Ely Shoshone Tribe
D. Crawford, Inter-Tribal Council of Nevada
H. Blackeye, Jr., Duckwater Shoshone Tribe
D. Eddy, Jr. Colorado River Indian Tribes
J. Leeds, Las Vegas Indian Center
W. Briggs, Ross, Dixon & Bell

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. However, during the conduct of the audit, the observers initiated an audit observer inquiry (AOI) identifying concerns about the current practice used by OQA and EM-5 for reviewing and approving exceptions to the QARD.

Additionally, the observers discussed OQA's and EM-5's roles in overseeing contractor activities at the various EM field offices. The EM-5 QA Director explained that EM-5 may no longer participate in audits of site contractors and that the field offices may have the responsibility to perform these audits. The observers recommended that, should EM-5 decide not to participate in audits of site contractors, either OQA or the EM-5 QA organization evaluate the need to oversee the initial field office audits and to determine the effectiveness of these audits.

Although the audit team identified two potential deficiencies, the observers believe that the audits performed by EM-5 were well-planned and adequately evaluated the implementation of the QARD at the various HLW processing sites. NRC will continue to interface with OCRWM and follow the progress that EM-5 is making to address the issues identified during this audit.

A written response to this letter and the enclosed report is not required; however, we do request that you respond to AOI No. EM-ARC-02-01, Sequence No. 1, provided to the audit team during audit and discussed in the attached report. If you have any questions, please contact Larry L. Campbell, of my staff at (301) 415-5000.

Sincerely,

C. William Reamer, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material Safety
and Safeguards

Enclosure: NRC Observation Audit Report
No. OAR-02-03, "Observation Audit
of the Office of Civilian Radioactive
Waste Management, Office of Quality Assurance,
Audit No. EM-ARC-02-01"

cc: See attached list

DISTRIBUTION:

FILE CENTER	HLWB r/f	DWM r/f	ACNW	PUBLIC	OSRs
LSN	CNWRA	CWReamer	KStablein	DBrooks	TEssig
SWastler	BSpitzberg	DDambly	MYoung	DHiggs	WSmith
KNaidu					

ADAMS Accession No.: ML

DOCUMENT NAME: S/DWM/HLWB/llc/EM Germantown Dec 2001.wpd

***See Previous concurrence**

This document is Non-Sensitive

OFC	HLWB*		Tech Editor*		HLWB		HLWB	
NAME	LLCampbell		EKraus		NKStablein		CWReamer	
DATE	12/31/01		12/31/01		01/10/02		01/10/02	

OFFICIAL COPY

ACNW: YES ☒ NO ☐ Delete file after distribution: Yes ☐ No ☐

1) This document should be made available to the PUBLIC. Yes - llc3

2) This document is related to the HLW program. It should be placed in the LSS. Yes - llc3

U.S. NUCLEAR REGULATORY COMMISSION
OBSERVATION AUDIT REPORT NO. OAR-02-03

"OBSERVATION AUDIT OF THE
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT,
OFFICE OF QUALITY ASSURANCE
AUDIT NO. EM-ARC-02-01"

 /RA/ 12/31/01
Larry L. Campbell
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

 /RA/ 12/26/01
Kamalakar Naidu
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

 /RA/ 12/26/01
Wilkins Smith
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

Reviewed and Approved by:

 /RA/ 01/10/02
N. King Stablein, Chief
Projects and Engineering Section
High-Level Waste Branch
Division of Waste Management

1.0 INTRODUCTION

Office of Environmental Management (Background)

In 1989, the Secretary of Energy created the Office of Environmental Restoration and Waste Management, later named the Office of Environmental Management (EM), to consolidate budgets and staff devoted to similar environmental tasks within the U.S. Department of Energy (DOE) into a single program office. The major categories of wastes controlled by EM include: high-level waste (HLW); transuranic waste; low-level waste; mixed low-level waste; 11e(2) byproduct material; hazardous waste; and other wastes. EM oversees all of DOE's HLW at the following four sites: a) Hanford Office of River Protection Site (Hanford); b) Idaho National Environmental and Engineering Laboratory (INEEL); c) The Savannah River Site's Defense Waste Processing Facility (Savannah River); and d) West Valley Demonstration Project (WVDP), a non-weapons site, owned by New York State and managed by DOE. Hanford manages the largest volume of HLW while Savannah River manages a larger amount of radioactivity in its HLW.

Under Federal law, DOE HLW may eventually be disposed of in a potential geologic repository at Yucca Mountain, Nevada, after it has been processed into a solid waste form. The DOE Office of Civilian Radioactive Waste Management (OCRWM) is responsible for: 1) characterizing the potential geologic repository at Yucca Mountain; 2) possibly constructing the geologic repository; and 3) disposing of DOE HLW, DOE spent nuclear fuel, and Naval spent nuclear fuel into the geologic repository. DOE began to vitrify the HLW in May 1996 at Savannah River and in July 1996 at the WVDP. Final treatment of HLW at Hanford and INEEL is now in the planning stage.

Performance of the Audit

Staff from the U.S. Nuclear Regulatory Commission (NRC), Division of Waste Management (DWM), observed DOE's OCRWM, Office of Quality Assurance's (OQA's), audit of activities regarding EM's Office of Safety, Health and Security's (EM-5's), implementation of the HLW Quality Assurance (QA) Program. This audit was conducted on December 11 through 14, 2001, at the EM offices in Germantown, Maryland.

The purpose of this audit was to evaluate the effectiveness of EM-5's implementation of the HLW QA Program and to determine if applicable requirements of the OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 10, were being met. The scope of the audit was to evaluate the implementation of the QARD for EM-5 activities controlling the processing of HLW at various sites such as the Savannah River and Hanford. Also, the audit evaluated action taken as a result of the findings and recommendations identified during previous OQA audits.

The NRC observers' (observers') objective was to assess whether OQA and EM-5 were properly implementing the requirements contained in Subpart G, "Quality Assurance," to Part 63, of Title 10 of the U.S. Code of Federal Regulations (10 CFR Part 63) and the provisions contained in the QARD.

This report presents the observers' determination of how effective the OQA audit was, and whether EM-5 implemented adequate QARD controls in the audited areas.

2.0 MANAGEMENT SUMMARY

Within the areas evaluated, the audit team identified two potential deficiencies. One potential deficiency identified that the files for certain Memoranda of Agreements (MOAs), between affected organizations, did not contain the revision history required by applicable EM-5 procedures. The second potential deficiency identified the following three problems within the area of training: 1) Certain training files were missing experience and education documentation; 2) QARD requirements for position descriptions were not met; and 3) Training matrixes do not address job responsibilities and functions.

The observers determined that OQA Audit EM-ARC-02-01 was well-planned and effectively executed. The audit team members were independent of the activities they audited and were knowledgeable in the QA and technical disciplines within the scope of the audit. The audit team members' qualifications were reviewed before the conduct of the audit, and found acceptable.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. However, during the conduct of the audit, the observers initiated an audit observer inquiry (AOI) identifying concerns about OQA's and EM-5's current practice for reviewing and approving exceptions to the QARD identified on an affected organization's QARD Requirements Matrix.

Additionally, the observers discussed OQA's and EM-5's roles in overseeing contractor activities at the various EM field offices. The EM-5 QA Director explained that EM-5 may no longer participate in audits of site contractors and that the field offices may have the responsibility to perform these audits. The observers recommended that, should EM-5 decide not to participate in audits of site contractors, either OQA or the EM-5 QA organization evaluate the need to oversee the initial field office audits and to determine the effectiveness of these audits.

Although the OQA audit team identified two potential deficiencies, the observers believe that the audits performed by EM-5 were well-planned and adequately evaluated the implementation of the QARD at the various HLW processing sites.

The staff will continue to interface with OCRWM and follow the progress that EM-5 is making to address the issues identified during this audit.

3.0 AUDIT PARTICIPANTS

3.1 Observers

Larry L. Campbell	Team Leader	NRC
Kamalakar Naidu	Team Member	NRC
Wilkins R. Smith (Part-Time)	Team Member	NRC
Jack D. Parrott (Entrance Meeting Only)	DWM Staff	NRC

3.2 OQA Audit Team

John R. Doyle	Audit Team Leader	OQA/Navarro Quality Services (OQA/NQS)
Marilyn A. Kavchak	Auditor	OQA/NQS
James E. Flaherty	Auditor	OQA/NQS

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

This OQA audit of EM-5 was conducted in accordance with OCRWM Quality Assurance Procedure (QAP) 18.2, "Internal Audit Program," and QAP 16.1Q, "Management of Conditions Adverse to Quality." The NRC staff's observation of this audit was based on NRC Manual Chapter 2410, "Conduct of Observation Audits," dated July 12, 2000.

4.1 Scope of the Audit

The scope of the audit included the following QARD elements: 1) Organization; 2) QA Program; 3) Implementing Documents; 4) Document Control; 5) Corrective Action; 6) QA Records; 7) Audits; and 8) High-Level Waste Form Production. Further, the audit evaluated the implementation of the QARD for EM-5 activities controlling the processing of HLW at various sites such as Savannah River and Hanford. Also, the audit evaluated action taken as a result of the findings and recommendations identified during previous OQA audits.

The observers focused their efforts on: 1) The organizational structure of EM-5 and the various field offices processing HLW; 2) The adequacy of EM-5's audits and oversight of the sites; and 3) EM-5's response and processing of past OQA audit findings.

The audit team and observers evaluated the implementation of the following procedures for the audited activities during the audit:

Procedures

OCRWM Procedures

- a) QAP-18.1Q, "Auditor Qualification."
- b) QAP-18.2Q, "Internal Audit Program."
- c) QAP-16.1Q, "Management of Conditions Adverse to Quality."

EM-5 Procedures

- a) QARD Requirements Matrix.
- b) Standard Practice Procedure (SPP) No. 1.02, "High-Level Waste Vitrification Program Organization," Revision 5.
- c) SPP No. 2.01, "Procedures and QARD Requirements Matrix," Revision 3.
- d) SPP No. 3.01, "Training," Revision 3.

- e) SPP No. 3.02, "Qualification and Certification Records," Revision 3.
- f) SPP No. 4.01, "Evaluation and Assessment Activities," Revision 2.
- g) SPP No. 4.02, "Audits," Revision 5.
- h) SPP No. 4.03, "Readiness Reviews and Surveillance," Revision 2.
- i) SPP No. 4.04, "Technical and QA Documents," Revision 4.
- j) SPP No. 5.01, "Deviations and Corrective Actions/Tracking System," Revision 2.
- k) SPP No. 5.02, "Stop Work Orders," Revision 2.
- l) SPP No. 6.01, "Distribution of Controlled Documents," Revision 3.
- m) SPP No. 7.01, "Quality Records," Revision 3.
- n) SPP No 8.01, "Differing Staff Opinions," Revision 2.

4.2 Conduct and Timing of the Audit

The audit was performed effectively and the audit team demonstrated a sound knowledge of the applicable EM-5 and OCRWM programs and procedures. The audit checklist was developed using the QARD and applicable EM-5 implementing procedures. Audit team members conducted thorough interviews; they challenged responses, when appropriate; and they effectively employed their detailed audit checklists. The observers concluded that the timing of the audit was appropriate for the auditors to evaluate ongoing EM-5 activities. The audit team and the observers caucused at the end of each day. Meetings between the audit team and EM-5 (with the observers present) were held, as necessary, to discuss the current audit status and preliminary findings.

4.3 Audit Team Qualification and Independence

Before the conduct of the audit, the qualifications of the audit team were reviewed for accuracy and completeness, in accordance with the requirements of QAP 18.1, "Auditor Qualification." The observers' and the NRC On-site Representatives' reviews included an examination of the training, education, and experience of the audit team members. The observers concluded that the audit team members had the necessary expertise to perform the audit and were qualified to audit EM-5 activities.

The observers reviewed organizational information and determined that the audit team members were independent of any direct responsibility for performing audited activities. The observers concluded that the auditors had sufficient authority and organizational freedom to make the audit process meaningful and effective.

4.4 Examination of QA Elements

4.4.1 Organization

Organizationally, DOE manages the HLW program through its Headquarters program offices and the many field and operations offices. Seven offices report to the Assistant Secretary for EM. EM has overall responsibility for developing, qualifying, and producing an acceptable HLW form for OCRWM. The HLW QA Program is managed by EM-5. EM-5 consists of a Safety and Health Team, Package Certification Team, Safeguards and Security Team, and Quality Systems Team. The Quality Systems Team oversees the programs in QA; 3D (data, decision, and documentation); Emergency Management; and Risk Management. QA in EM-5 has diverse responsibilities that include providing guidance and support on matters affecting HLW acceptance QA and interfacing and program coordination with other QA programs, both within EM and across the DOE complex. The HLW QA Manager is located within EM-5.

There are several other offices within EM that are involved in the budgeting, planning, and execution of the HLW vitrification projects. The Office of Integration and Disposition has the primary responsibility for coordinating the inventory of HLW for the potential geological repository with OCRWM. The Office of Site Closure's Ohio Office is responsible for WVDP. The Office of Project Completion's Idaho Office, Savannah River Office, and River Protection Office are responsible for the remainder of EM's HLW vitrification projects.

The audit team and observers reviewed several of the MOAs that describe, in part, the quality and technical agreements for a defined scope of work. During the previous audit (EM-ARC-01-09 performed in June 2001) of EM-5, the audit team identified, and discussed, with EM-5, that the MOAs did not reflect the current organizational structure within EM. The previous audit team identified this condition as a potential deficiency. During this audit, it was found that this deficiency remained open, and that OCRWM would be responsible to close out this deficiency.

During this audit, OQA and EM-5 discussed EM-5 QA resources for implementing its oversight activities. The EM-5 QA Manager explained that, presently, all contractor monies for QA support had been frozen and that management had asked him to evaluate and review the resources available within EM for supporting QA activities. Further, it was explained that should qualified QA resources not be available within EM and justification provided, EM management would release monies for contract support.

Also, the EM-5 QA Manager discussed the possibility that EM-5 may no longer participate in EM field office audits of their contractors, and that the field offices may have all responsibility for ensuring that their contractors are effectively implementing the QARD. The observers recommended that, should EM-5 no longer participate in the audits of site contractor activities, OQA and EM-5 evaluate the need to oversee the initial field office audits of their contractors and to determine the effectiveness of these audits.

The observers agreed with the audit team's findings in this area.

4.4.2 QA Program and the QARD Requirements Matrixes

During the previous OQA audit (June 2001) of EM-5, the audit team evaluated whether EM-5 had provided acceptable, appropriate justifications for any exceptions to the QARD. The June 2001 audit team identified one deficiency in this area:

EM-5 had taken exception to the QARD requirements for trending. EM-5 only oversaw the trending function and had delegated the responsibility for trending to the QA organizations at the various HLW processing sites. The audit team considered this to be an inappropriate delegation, inconsistent with the intent of the QARD. The audit team identified that trending should be at the EM-5 level, as well as at the site level.

The above OQA audit finding could not be closed during this audit and remains open.

During this audit, OQA and EM-5 audit personnel stated that their present practice for reviewing the QARD Requirements Matrixes was to review the matrixes during their annual audits of the affected organizations responsible for the matrixes.

The observers noted that reviewing QARD Requirements Matrixes, including any exceptions taken by the affected organizations and any requirements identified as not applicable, once a year, during the conduct of an audit, is a concern. The observers noted that this practice may result in an unacceptable exception or a requirement incorrectly identified as not applicable being implemented for almost a year.

Further, the observers noted that the OQA audit checklist for Audit EM-ARC-02-01 and several fiscal year 2001 EM-5 audit checklists, used for reviewing QARD Requirements Matrixes, do not appear to meet applicable review provisions contained in Section 2.2.10 of the QARD. For example, QARD Section 2.2.10.A requires that review criteria be established before performing the QARD Requirements Matrix review and that the criteria shall consider applicability, correctness, technical adequacy, completeness, accuracy, and compliance with established requirements. Based on the observers' review of the audit checklists, it was found that the checklist did not appear to address or identify acceptance criteria to be used by the audit team when reviewing the matrixes. Further, the observers noted that, as required by QARD Section 2.2.10.A, the audit checklist should contain acceptance criteria or guidance to evaluate the acceptability of exceptions or alternatives to QARD requirements.

During the audit, the observers noted that they believed these acceptance criteria could include considerations such as the following: applicable regulations are not violated; applicable DOE policies and practices are met; equivalent levels of QA are provided; exceptions or alternatives are or are not within the affected organization's work scope; and under certain circumstances, obtain guidance from the OQA QA Director for acceptance of alternatives and exceptions. Further, it was not clear to the observers if the review provisions contained in Section 2.2.10 are entirely applicable for reviewing exceptions, alternatives, or requirements not within the scope of the affected organization's work scope. Because some exceptions or alternatives may result in a reduction of a QARD requirement, the observers suggested that OQA evaluate the review provisions contained in QARD Section 2.2.10 and determine if they need to be revised or supplemented when they are used for the review of QARD Requirements Matrixes.

As a result of the above discussion, the observers generated AOI No. EM-ARC-02-01, Sequence No. 1, Exhibit 1 to this report, which states in part:

“It appears that the review and acceptance of exceptions or alternatives to QARD requirements, and the review of QARD [Requirements] Matrixes, as presently performed during OQA and EM-5 audits, is an area [are areas] requiring improvement. It is recommended that, as a minimum, OQA evaluate the need for the QARD be revised to require formal approval of exceptions or alternatives to QARD requirements (as applicable by OQA or EM-5) before they are implemented by the affected organization. Further, it is recommended that OQA evaluate the review requirements contained in QARD Section 2.2.10 and determine if they are acceptable when used for the review of QARD Requirements Matrixes. If QARD Section 2.2.10 is determined to be to be acceptable for this review, then applicable OQA and EM-5 audit checklists, used to review QARD Requirements Matrixes, need to be revised to address QARD Section 2.2.10 review requirements.”

Other than the generation of the above AOI, the observers agreed with the audit team’s findings in this area.

4.4.3 EM-5 Audit Reports

During the audit, the audit team and observers reviewed several fiscal year 2001 EM-5 audit reports and their completed checklists. The audit team concluded that these audits were performed in accordance with applicable QARD and EM-5 procedures requirements. Further, the audit team confirmed that findings were properly classified as deviations and observations.

The observers agreed with the audit team’s findings in this area with the exception that the audit checklists do not appear to provide the acceptance criteria for the review of QARD Requirements Matrixes, as discussed in Section 4.4.2 of this report.

4.4.4 EM-5 Training and Qualification Records

The audit team and observers reviewed the training and qualification records for several of the EM-5 audit team members. The audit team and observers found it difficult to relate the training matrix developed by EM-5 to individuals performing quality functions. The EM-5 QA Manager described the method he uses to ensure individuals are qualified to perform assigned quality activities and explained the contents of personnel training and qualification files. Notwithstanding these discussions and explanations, the audit team identified three problems resulting in a potential deficiency in this area: 1) Certain training files were missing experience and education documentation; 2) QARD requirements for position descriptions were not met; and 3) Training matrixes do not address job responsibilities and functions.

The observers agreed with the audit team findings in this area.

4.4.5 Review of Deficiencies from Past Audits

The audit team and observers reviewed EM-5’s processing and corrective action for the following deficiency reports (DRs) identified during the June 2001 OQA audit:

DR No. EM-01-D-89, dated June 21, 2001, identified that the MOA for coordination of QA activities between OCRWM and the Office of Waste Management had not been revised to reflect the current organizational structure. Likewise, the MOAs for the coordination and implementation of QA activities between the HLW Field Offices and EM were found to be outdated.

DR No. EM-01-D-90, dated June 21, 2001, identified that no process existed for EM-5 to evaluate trends.

DR No. EM-01-D-91, dated June 21, 2001, identified that EM-5 failed to take timely corrective action for DR No. EM-00-D-101 (scheduled for completion by March 1, 2001).

Although EM-5 had been working to close these DRs, the audit team found the actions taken to date were not adequate to close out the DRs. During the audit, EM-5 indicated that it would request extensions for closing out the DRs.

The observers agreed with the audit team's findings in this area and expressed a concern about timely corrective action because the DRs were still open.

4.4.6 Summary: Deficiencies and Recommendations Identified by the DOE Audit Team

During this audit, the audit team identified two potential deficiencies. One potential deficiency identified that the files for certain MOAs, between affected organizations, did not contain the revision histories required by applicable EM-5 procedures. The second potential deficiency identified the following three problems within the area of training: 1) Certain training files were missing experience and education documentation; 2) QARD requirements for position descriptions were not met; and 3) Training matrixes do not address job responsibilities and functions.

5.0 NRC STAFF FINDINGS

The observers determined that OQA Audit EM-ARC-02-01 was effective in determining the level of compliance of EM-5 activities associated with the oversight of HLW processing activities.

The observers agreed with the audit team's conclusions, findings, and recommendations presented at the audit exit. However, during the conduct of the audit, the observers initiated an AOI identifying concerns about the current practice used by OQA and EM-5 for reviewing and approving exceptions to the QARD.

The observers discussed OQA's and EM-5's roles in overseeing contractor activities at the various EM field offices. The EM-5 QA Director explained that EM-5 may no longer participate in audits of site contractors and that the field offices may have the responsibility to perform these audits. The observers recommended that, should EM-5 decide not to participate in audits of site contractors, either OQA or the EM-5 QA organization evaluate the need to oversee the initial field office audits and to determine the effectiveness of these audits.

Although the OQA audit team identified two potential deficiencies, the observers believe that the audits performed by EM-5 were well-planned and adequately evaluated the implementation of the QARD at the various HLW processing sites.

The observers agreed with the audit team's conclusion that the QARD had been satisfactorily implemented except for the identified potential deficiencies. NRC will continue to interface with OCRWM and follow the progress that EM-5 is making to address the issues identified during this audit.

5.1 NRC Audit Exit Summary

During the audit exit, the observers expressed appreciation for the excellent cooperation and responsiveness provided to them during their observation activities. In addition, the observers stated that they agreed with the audit team findings and recommendations, as presented at the audit exit. Also, during the audit and audit exit meetings, the observers discussed the following:

- Notwithstanding the findings identified by the audit team, the observers believed that the audits performed by EM-5 were well-planned and adequately evaluated the implementation of the QARD at the various HLW processing sites. However, the observers noted that they were concerned about the methods used by OQA and EM-5 for reviewing and approving exceptions to the QARD as previously discussed in this report and documented in AOI No. EM-ARC-02-01, Sequence No. 1.
- The observers noted that during the audit, they had discussed with EM-5 management the resources available for implementing the HLW QA program. EM-5 management agreed that QA should be pro-active rather reactive, thus detecting problems before they evolve into significant conditions adverse to quality. Additionally, the observers stated that EM-5 management should continue to review resources designated for QA activities to ensure that they are adequate.
- Should EM-5 decide to not participate in EM field office audits of its contractors, the observers recommended that OQA and EM-5 evaluate the need to provide oversight of the initial EM field office audits of its contractors and to determine the effectiveness of these audits.
- NRC may observe EM-5 and EM field office audit activities during fiscal year 2002, as provided for in the various MOAs with the HLW sites.
- The staff will continue to interface with OCRWM and follow the progress that EM-5 is making to address the issues identified during this and previous OQA audits.

5.2 AOIs

During the audit, the observers initiated AOI No. EM-ARC-02-01, Sequence No. 1, as discussed in Section 4.4.2 of this report, and provided as Exhibit 1 to this report. OCRWM is requested to provide a response to this AOI.

5.3 Open AOIs from Previous NRC Observations

There are no open AOIs from previous NRC audits.

6.0 EXHIBITS

Exhibit 1: AOI No. EM-ARC-02-01, Sequence No. 1